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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/620,055 | 07/14/2003 | Timothy J. Ohara | LSI0054/US/2 | 7665 |

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| EXAMINER | |
|---|---|
| NOGUEROLA, ALEXANDER STEPHAN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1753 | |

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/620,055 | OHARA ET AL. | |
| | Examiner | Art Unit | |
| | ALEX NOGUEROLA | 1753 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *preliminary amndt. of July 14, 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/09/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: IDSs of 8/01/2005, 12/16/2005,10/21/2005,01/06/2006, and 03/17/2006.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jina (US 6,060,323) in view of Hodges et al. (WO 9700441 A1) ("Hodges").

Addressing claim 21, Jina discloses an electrochemical test strip (16) comprising

(a) spaced apart working (64) and reference electrodes (66); and

(b) a reagent mixture comprising:

(i) a redox couple (col. 11:50-54 and col. 4:9-17)

(i) a coagulation agent (col. 11:50-61, col. 9:45-58; col. 10:6-16).

Jina does not mention (a) having the working and reference electrodes oppositely spaced apart, and (b) having the working and reference electrodes spaced apart from about 50 to 750μm.

Hodges discloses an electrochemical cell comprising working and reference electrodes oppositely spaced apart from about 50 to 750μm. See Figures 1-4 and the abstract. It would have been obvious to one with ordinary skill in the art at the time of the invention to have the working and reference electrodes oppositely spaced apart from about 50 to 750μm as taught by Hodges in the invention of Jina because as taught by Hodges, "This ... allows the diffusion coefficient and concentration of the redox species (mediator) to be measured independently of sample variations and therefore

improves accuracy and reliability" (page 6, lines 12-15), Jina discloses using the same redox couple as Hodges (ferricyanide – page 6, lines 7-11 and in Jina col. 11:50-54) and measures diffusion properties of the redox couple (col. 9:25-31 and col. 10:36-40), and because the cell of Hodges can be used with blood samples (page 6, lines 16-19).

It should be noted that although the embodiment in Figure 6 of Jina shows separate counter and reference electrodes Hodges states, "For preference the cell comprises a working electrodes and counter/reference electrodes. If a reference electrode separate from a counter electrode is used, then the reference electrode may be in any convenient location in which it is in contact with the sample in the sensor." See page 6, lines 3-6.

Addressing claim 22, for the additional limitation of this claim see in Jina col. 10:6-16.

Addressing claim 23, for the additional limitation of this claim see in Jina col. 11:50-54. Also see in Hodges page 6, lines 7-11.

Addressing claim 24, Jina as modified by Hodges does not mention the volume of the electrochemical cell. However, because Hodges states that the electrodes may be spaced apart by only 20 μm (page 8, lines 12-14), barring evidence to the contrary,

such as unexpected results, the clamed volume range for the cell is only a matter of scaling the cell volume to the expected sample volume range.

Addressing claim 25, Jina discloses a meter for detecting a change in viscosity of a fluid sample (abstract), the meter comprising:

(a) means for applying an electric potential to an electrochemical cell made up of spaced apart working and reference electrodes and comprising a fluid sample (Figures 1, 2, and 6; col. 8:50-58; and col. 7:18-22); and

(b) means for measuring cell current between the spaced working and reference electrodes (vol. 6:54 – col. 7:8).

Jina does not *mention* means for detecting a change in the measured cell current and means for relating the change in measured cell current to a change in viscosity of the fluid sample. However, these means are arguably implied or clearly obvious because Jina discloses, "The processoer **32** contains a program which includes, but is not limited to, *interpreting* the current off the electrodes, ...[emphasis added]" (col. 7:4-8) and

> Until such time when clotting is complete, there may be a slight increase in the current of the clot due to aggregation of the elecoactive species in spite of restricted ionic mobility and or diffusion. Such a current time profile is extremely useful in determining the onset of clotting as well as the endpoint of the clotting process and could conceptually provide a very accurate means for determining the onset of clotting as well as the endpoint of the clotting times in PT, APTT and other clotting assays. The sensitivity of these types of current or voltage time measurements is inherent in the direct measurement technique ..." (col. 9:49-61).

In other words, it would have been obvious to one with ordinary skill in the art at the time of the invention to provide in Jina means for detecting a change in the measured cell current and means for relating the change in measured cell current to a change in viscosity of the fluid sample because Jina discloses means for interpreting the measured current and the changes in the current profile reflect different stages of clotting. Thus, clotting can be monitored with such means.

Jina also does not mention having the means for applying an electric potential to an electrochemical cell configured for an electrochemical cell made up of oppositely spaced apart working and reference electrodes. In all of the Jina embodiments the electrodes are on the same plane. See Figures 2-5.

Hodges discloses an electrochemical cell comprising working and reference electrodes oppositely spaced apart from about 50 to 750μm. See Figures 1-4 and the abstract. It would have been obvious to one with ordinary skill in the art at the time of the invention to have the working and reference electrodes oppositely spaced apart from about 50 to 750μm as taught by Hodges in the invention of Jina (and so of course the electrical cell contacts in the meter of Jina oppositely spaced) because as taught by Hodges, "This ... allows the diffusion coefficient and concentration of the redox species (mediator) to be measured independently of sample variations and therefore improves accuracy and reliability" (page 6, lines 12-15), Jina discloses using the same redox couple as Hodges (ferricyanide – page 6, lines 7-11 and in Jina col. 11:50-54) and measures diffusion properties of the redox couple (col. 9:25-31 and col. 10:36-40), and because the cell of Hodges can be used with blood samples (page 6, lines 16-19).

It should be noted that although the embodiment in Figure 6 of Jina shows separate counter and reference electrodes Hodges states, "For preference the cell comprises a working electrodes and counter/reference electrodes. If a reference electrode separate from a counter electrode is used, then the reference electrode may be in any convenient location in which it is in contact with the sample in the sensor." See page 6, lines 3-6.

Addressing claim 26, for the additional limitation of this claim see in Jina col. 1:30-42; col. 9:45-58; and col. 10:6-16.

Addressing claim 27,Jina discloses a kit for use in detecting a coagulation event in a blood sample (the abstract), the kit comprising

(a) at least one electrochemical test strip comprising an electrochemical cell (Figure 6) comprising

(i) spaced apart working and reference electrodes (Figure 6);

(ii) a reagent mixture comprising a redox couple and a coagulation catalyzing agent; and

(iii) a means for obtaining a sample (col. 12:25-30).

Jina does not mention (a) having the working and reference electrodes oppositely spaced apart, and (b) having the working and reference electrodes spaced apart from about 50 to 750μm.

Hodges discloses an electrochemical cell comprising working and reference electrodes oppositely spaced apart from about 50 to 750μm. See Figures 1-4 and the abstract. It would have been obvious to one with ordinary skill in the art at the time of the invention to have the working and reference electrodes oppositely spaced apart from about 50 to 750μm as taught by Hodges in the invention of Jina because as taught by Hodges, "This ... allows the diffusion coefficient and concentration of the redox species (mediator) to be measured independently of sample variations and therefore improves accuracy and reliability" (page 6, lines 12-15), Jina discloses using the same redox couple as Hodges (ferricyanide – page 6, lines 7-11 and in Jina col. 11:50-54) and measures diffusion properties of the redox couple (col. 9:25-31 and col. 10:36-40), and because the cell of Hodges can be used with blood samples (page 6, lines 16-19).

It should be noted that although the embodiment in Figure 6 of Jina shows separate counter and reference electrodes Hodges states, "For preference the cell comprises a working electrodes and counter/reference electrodes. If a reference electrode separate from a counter electrode is used, then the reference electrode may be in any convenient location in which it is in contact with the sample in the sensor." See page 6, lines 3-6.

Addressing claim 28, for the additional limitation of this claim see in Jina Figure 1.

Addressing claim 29, Jina discloses a system comprising

(1) an electrochemical test strip (16) comprising

(a) spaced apart working (64) and reference electrodes (66); and

(b) a reagent mixture comprising:

(i) a redox couple (col. 11:50-54 and col. 4:9-17)

(i) a coagulation agent (col. 11:50-61, col. 9:45-58; col. 10:6-16); and

(2) a meter (Figure 1).

Jina does not mention (a) having the working and reference electrodes oppositely spaced apart, and (b) having the working and reference electrodes spaced apart from about 50 to 750μm.

Hodges discloses an electrochemical cell comprising working and reference electrodes oppositely spaced apart from about 50 to 750μm. See Figures 1-4 and the abstract. It would have been obvious to one with ordinary skill in the art at the time of the invention to have the working and reference electrodes oppositely spaced apart from about 50 to 750μm as taught by Hodges in the invention of Jina because as taught by Hodges, "This ... allows the diffusion coefficient and concentration of the redox

species (mediator) to be measured independently of sample variations and therefore improves accuracy and reliability" (page 6, lines 12-15), Jina discloses using the same redox couple as Hodges (ferricyanide – page 6, lines 7-11 and in Jina col. 11:50-54) and measures diffusion properties of the redox couple (col. 9:25-31 and col. 10:36-40), and because the cell of Hodges can be used with blood samples (page 6, lines 16-19).

It should be noted that although the embodiment in Figure 6 of Jina shows separate counter and reference electrodes Hodges states, "For preference the cell comprises a working electrodes and counter/reference electrodes. If a reference electrode separate from a counter electrode is used, then the reference electrode may be in any convenient location in which it is in contact with the sample in the sensor." See page 6, lines 3-6.

It should also be noted that the preamble limitation that the system is "for use in determining the concentration of an analyte in a physiological sample," is an intended use that does not further structurally limit the system and thus a use for which the system of Jina as modified by Hodges is capable of.

Addressing claim 30, Jina discloses a system comprising

(1) an electrochemical test strip (16); and

(2) a meter comprising:

(a) means for applying an electric potential to an electrochemical cell made up of spaced apart working and reference electrodes and

comprising a fluid sample (Figures 1, 2, and 6; col. 8:50-58; and col. 7:18-22); and

(b) means for measuring cell current between the spaced working and reference electrodes (vol. 6:54 – col. 7:8).

Jina does not *mention* means for detecting a change in the measured cell current and means for relating the change in measured cell current to a change in viscosity of the fluid sample. However, these means are arguably implied or clearly obvious because Jina discloses, "The processor **32** contains a program which includes, but is not limited to, *interpreting* the current off the electrodes, ...[emphasis added]" (col. 7:4-8) and

> Until such time when clotting is complete, there may be a slight increase in the current of the clot due to aggregation of the electroactive species in spite of restricted ionic mobility and or diffusion. Such a current time profile is extremely useful in determining the onset of clotting as well as the endpoint of the clotting process and could conceptually provide a very accurate means for determining the onset of clotting as well as the endpoint of the clotting times in PT, APTT and other clotting assays. The sensitivity of these types of current or voltage time measurements is inherent in the direct measurement technique ..." (col. 9:49-61).

In other words, it would have been obvious to one with ordinary skill in the art at the time of the invention to provide in Jina means for detecting a change in the measured cell current and means for relating the change in measured cell current to a change in viscosity of the fluid sample because Jina discloses means for interpreting the measured current and that the changes in the current profile reflect different stages of clotting. Thus, clotting can be monitored with such means.

Jina also does not mention having the means for applying an electric potential to an electrochemical cell configured for an electrochemical cell made up of oppositely spaced apart working and reference electrodes. In all of the Jina embodiments the electrodes are on the same plane. See Figures 2-5.

Hodges discloses an electrochemical cell comprising working and reference electrodes oppositely spaced apart from about 50 to 750µm. See Figures 1-4 and the abstract. It would have been obvious to one with ordinary skill in the art at the time of the invention to have the working and reference electrodes oppositely spaced apart from about 50 to 750µm as taught by Hodges in the invention of Jina (and so of course the electrical cell contacts in the meter of Jina oppositely spaced) because as taught by Hodges, "This ... allows the diffusion coefficient and concentration of the redox species (mediator) to be measured independently of sample variations and therefore improves accuracy and reliability" (page 6, lines 12-15), Jina discloses using the same redox couple as Hodges (ferricyanide – page 6, lines 7-11 and in Jina col. 11:50-54) and measures diffusion properties of the redox couple (col. 9:25-31 and col. 10:36-40), and because the cell of Hodges can be used with blood samples (page 6, lines 16-19).

It should be noted that although the embodiment in Figure 6 of Jina shows separate counter and reference electrodes Hodges states, "For preference the cell comprises a working electrodes and counter/reference electrodes. If a reference electrode separate from a counter electrode is used, then the reference electrode may be in any convenient location in which it is in contact with the sample in the sensor." See page 6, lines 3-6.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 29 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The preamble to claims 29 and 30 require that the systems be "for use in determining the concentration of an analyte in a physiological sample." There is no mention of such a use in the original disclosure. The only originally disclosed uses of the system are for determining coagulation in blood or viscosity change in a fluid.

7. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention: Claim 30 is a system for use in determining the concentration of an analyte in a physiological sample. However, the claim does not require means for determining the concentration of an analyte, but means for relating the change in measured cell current to a change in viscosity of the fluid sample.

***Claim Objections***

8. Claims 25 and 27 are objected to because of the following informalities:

a) Claim 25: in line 4 "space" should be -- spaced --; and

b) Claim 27: in line 7 "on" should be -- one --.

Appropriate correction is required.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
August 17, 2006